IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

INGENUS PHARMACEUTICALS, LLC,

Plaintiff,

v.

C.A. No. 24-1025-JLH

HETERO USA, INC., HETERO LABS LTD., and HETERO LABS LTD. UNIT-VI,

Defendants.

DECLARATION OF L. ROMAN RACHUBA II IN SUPPORT OF PLAINTIFF INGENUS PHARMACEUTICALS, LLC'S MOTION TO STAY

- I, L. Roman Rachuba II, upon personal knowledge or information and belief, state as follows:
- 1. I am an attorney and a member of the bar of the District of Columbia. I am a partner with Sughrue Mion, PLLC, and represent Plaintiff Ingenus Pharmaceuticals, LLC ("Ingenus" or "Plaintiff") in this litigation. I am over the age of 18 and otherwise competent to make this declaration.
- 2. To date, defendants Hetero USA, Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI. ("Hetero" or "Defendants") have not produced any "documents related to the research and development of its ANDA product," despite Defendants committing to do so in their April 25, 2025 Opposition (D.I. 42) to Ingenus's Discovery Motion (D.I. 39).
- 3. To date, Defendants have not produced an organizational chart with employee names, despite the Court having ordered them to do so in the April 28, 2025 Order. D.I. 43. Nor have Defendants produced any documents concerning actions taken with respect to their paragraph IV certification.

- 4. To date, Defendants have not updated their discovery responses to expressly state whether they are withholding responsive information, despite the Court having ordered them to do so in the April 28, 2025 Order. D.I. 43.
- 5. To date, Defendants have not produced any samples of their Cyclophosphamide Solution; 500mg/2.5ml (200mg/ml), lgm/5ml (200mg/ml), and 2gm/10ml (200mg/ml) ("Defendants' ANDA Products"), despite agreeing to do so in an April 2, 2025 correspondence to Ingenus.
- 6. On April 28, 2025, following the Court's Order of the same day (D.I. 43), Ingenus requested (1) that Defendants advise when they would supplement their document production and interrogatory responses; and (2) that Defendants confirm they would provide samples of their ANDA Products. Defendants did not respond.
- 7. On May 6, 2025, Ingenus requested to meet and confer with Defendants on these discovery issues. Again, Defendants did not respond.
- 8. On May 16, 2025, Ingenus again requested to meet and confer with Defendants on the outstanding discovery issues, but again, Defendants did not respond.
- 9. Due to Defendants' failure to abide by their discovery obligations, discovery in this case is effectively stayed.
- 10. At the current pace of discovery, the Parties will be unable to meet current claim construction and document production deadlines.
- 11. On May 16, 2025, Defendants contacted Ingenus, requesting that Ingenus stipulate to invalidity of the '952 Patent. Defendant did not respond to the outstanding discovery issues. Ingenus responded May 20, 2025, stating that Ingenus would not agree to a stipulation of invalidity.

- 12. The Parties met and conferred on Defendants' request for a stipulation of invalidity on May 30, 2025, and Defendants informed Ingenus of their intent to seek summary judgment of invalidity. Ingenus agreed to not oppose Defendants' request for leave to file their proposed motion, and Defendants agreed to a proposed stay of all current deadlines in the case pending resolution of any summary judgment motion. Although Ingenus proposed that the parties confer on the preparation of the joint claim construction chart as required by the Scheduling Order (D.I. 20) at the conference, Defendants did not respond to this request, and the joint claim construction chart was not discussed at the May 30, 2025 meet and confer.
- 13. On June 4, 2025, Defendants advised Ingenus that they no longer agreed that "an indefinite stay is appropriate." The following day, Ingenus again sought to confer with Defendants about the pending dates on the Scheduling Order relevant to claim construction.
- 14. On June 9, 2025, the parties agreed to submit a joint letter to the Court requesting: (1) that certain deadlines in the case be pushed back six weeks to accommodate briefing on Defendants' proposed summary judgment motion, and (2) a teleconference on how best to handle briefing on the issue, particularly in light of Ingenus's proposed motion to stay all deadlines in the case pending resolution of the appeal in *Ingenus Pharm., LLC v. Nexus Pharm., Inc.*, No. 1:22-cv-02868 (N.D. Ill.).
- 15. That same day, Defendants provided to Ingenus's Delaware counsel a proposed joint letter to the Court, requesting authorization to its submit its proposed letter as joint request made on behalf of all parties.
- 16. Ingenus responded next day on June 10, 2025, (1) requesting that all counsel be included on substantive communications in this case; (2) to inform Defendants that it would not join Defendants in their request for a status conference or schedule modification, but that it would

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not oppose either request; and (3) advising that it would not oppose Defendants' request for leave

to file their proposed summary judgment motion. Ingenus advised that Defendants did not have

permission to sign on Ingenus' behalf or represent that the letter is joint.

17. Defendants' June 10, 2025 letter (D.I. 48) falsely indicated that "Ingenus [] does

not oppose Hetero filing a motion for summary judgment." As discussed at the June 9, 2025 meet

and confer, and reaffirmed in the June 9, 2025 correspondence, Ingenus informed Defendants that

it did not oppose Defendants seeking leave to file its proposed summary judgment motion. Ingenus

did not indicate that it would not oppose filing the summary judgment motion itself.

On June 11, 2025, Ingenus requested that Defendants withdraw the June 9, 2025 18.

letter to the Court (D.I. 48) based on the misrepresentation. The same day, Defendants advised that

they would not do so.

At present, and to the best of Ingenus' knowledge, Defendants do not have FDA 19.

approval for their ANDA Products.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: June 13, 2025

/s/ L. Roman Rachuba II

L. Roman Rachuba II

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